

FURLS Device Registration & Listing Initial Registration

U.S. Food and Drug Administration
Center for Devices and Radiological Health

Division of Industry and Consumer Education (DICE)

Instructions for Domestic, First Registration in Account

This tutorial should only be used when 1) registering a facility that is located in the U.S.; 2) you have already paid the annual registration user fee and received your Payment Identification Number (PIN) and Payment Confirmation Number (PCN); and, 3) the owner/operator has no other registered facilities.

Step 1: Click <https://www.access.fda.gov/oa/> to open the FDA Industry Systems Website.

If you have created an account prior to starting this tutorial, enter the account ID and password, click "I Understand" and then click on the Login button.

If you have not yet created an account, click on "Create New Account" and follow the prompts until you get to the Account Management page.

Proceed to Step 2.

The screenshot shows the FDA Industry Systems Online Account Administration (OAA) website. The header includes the U.S. Department of Health and Human Services logo and the FDA OAA logo. The main heading is "FDA Industry Systems". Below this, there are two main sections: "Login" and "New User".

Login Section:

- Text: "Existing account holders, enter your account ID & password."
- Form fields: "Account ID" and "Password".
- Text: "Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties."
- Buttons: "I understand." (with a checkbox), "Login", and "Forgot Password".

New User Section:

- Text: "Create New Account" (with a plus icon).
- Buttons: "See Instructions", "See Tutorials", and "Help Desk".

Callouts:

- Callout 1 (pointing to the Login section): "If you have created an account prior to starting this tutorial, enter the account ID and password. Then click 'I Understand' and 'Login' to open the Account Management page."
- Callout 2 (pointing to the New User section): "If you have not yet created an account, click 'Create New Account' and follow the prompts until you get to the Account Management page."

Warning Text:

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Footer:

FDA Accessibility Browser Requirements FAQ Help Desk Privacy

Step 2: Click "Device Registration & Listing" to begin the registration.

Proceed to Step 3.

Note: If you have only created an owner/operator account, the same contact information will appear on the registration record for both the owner/operator and official correspondent. If a different person is acting as official correspondent, you must create a sub account for that person before beginning the registration process.

Account Management



Account Management ⓘ

Edit Account Profile

Change My Password

Update System Access

Create a Subaccount

Deactivate a Subaccount

Reactivate a Subaccount

Welcome to the FDA Industry Systems. You are logged in as **san1169** for **SANCO**.

You may choose an option on the left to manage your account or select an FDA system below.
To obtain access to available FDA systems, choose the **Update System Access** option to add the FDA system to your account.

CDRH - Center for Device and Radiological Health

Click to launch the Application(s)

☒ Device Registration and Listing Module

☐ Laboratory Developed Test Notification

☐ CDRH Export Certification Application and Tracking System

Wed Aug 05 09:05:04 EDT 2015

Step 3: Review "Important Messages" and click "Continue" to proceed to the DRLM Main Menu. Proceed to Step 4.

Note: You must pay the fee to receive your Payment Identification Number (PIN) & Payment Confirmation Number (PCN) before you can register your facility.



IMPORTANT MESSAGES

NEW: The CDRH Learn Device Establishment Registration and Listing Course has been updated with the current registration and listing requirements. Please visit this website <http://www.fda.gov/Training/CDRHLearn/ucm162015.htm> to view the course.

The FDA Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012. This law includes the Medical Device User Fee Amendments of 2012 (MDUFA III) as well as other medical device provisions. MDUFA III mandates that, beginning in Fiscal Year 2013, an annual registration user fee be paid for all types of establishments.

The fee for FY 2014 is \$3,313. There is no reduction in this fee for small businesses or any other groups. For more information about User Fees and MDUFA III see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAll/default.htm>

You must pay the fee before registering a new establishment or updating your existing registration(s) and/or listing(s) for FY 2014. If you have not paid the fee, please visit this website. For assistance with paying the fee, please send an email to users@fda.gov.

FDA primarily communicates with firms by email. To ensure that we have the correct email for your account, please click on the FURLS link at the top of this page. Then click on the "Update Email" link.

If you
regi
Cor
DRL

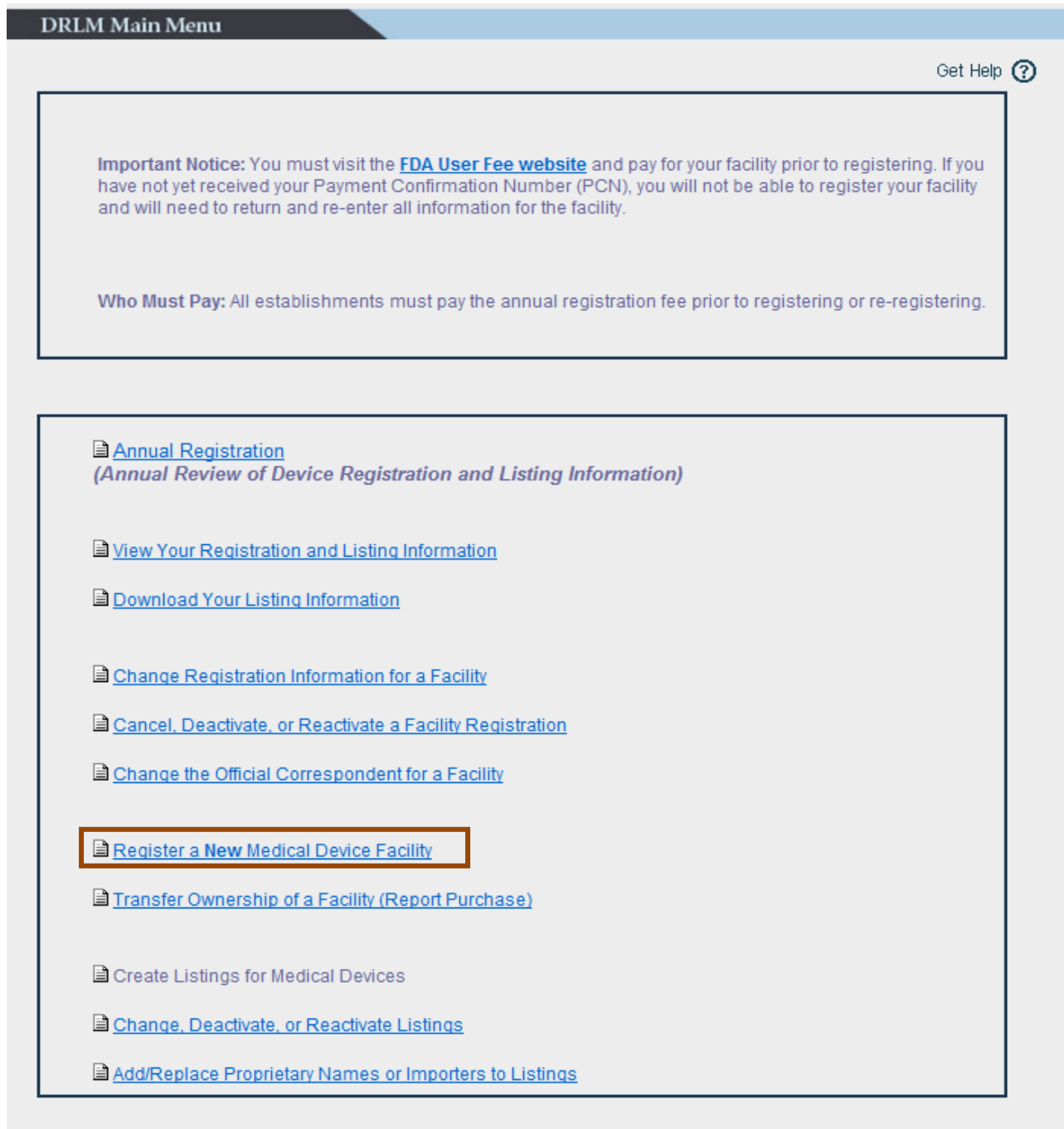
Click on this link if you need to pay the fee to get your PIN and PCN. Clicking the link will log you out of FURLS. After you get your PIN and PCN, you will need to log back into FURLS to register the facility.

registering or re-
(PIN) and Payment
n below to proceed to the

Please note a new feature has been added: You can now download all of your up-to-date listing information in Excel format. Just click "Download Your Listing Information", which is the third choice on the DRLM Main Menu.

> CONTINUE

Step 4: Review the "Important Notice" at the top of the DRLM Main Menu screen. Click on "Register a New Medical Device Facility". Proceed to Step 5.



Step 5: If the **facility was previously registered**, enter the Registration Number or Owner/Operator Number and click "Search." If the **facility has not been registered**, leave the search fields empty and click "No Existing Registration or OO Number" and follow the prompts to register. Proceed to Step 6.

DRLM
Device Registration & Listing Module

 **FDA** FURLS HOME
DRLM HOME

Register Your Facility Get Help ?

Register a New Facility

If you already have a Registration Number or Owner Operator Number, enter it and click Search.
If you do not have a Registration Number or Owner Operator Number, click here.

Enter Registration Number or Owner Operator Number if previously registered. Then click "Search."

Registration Number OR Owner Operator Number

If an establishment at this address has previously been registered with FDA as a device facility, but you do not know your Registration Number or Owner Operator Number, please send an email to reglist@cdrh.fda.gov for assistance. Do not create a new registration if a facility has been registered at your address.

Click here if your facility has never been registered.

[< CANCEL - RETURN to MAIN MENU](#) [> SEARCH](#) [> NO EXISTING REGISTRATION OR OO NUMBER](#)

Step 6: The Registration Requirements page provides links to pay the annual registration user fee, to determine if your product is exempt, to get your FDA product codes, and to register your facility. If you have both your PIN and PCN, and have determined your device listing information, including the facility activities, click "Register My Facility". Proceed to Step 7.

DRLM

Device Registration & Listing Module



FURLS HOME
SYSTEM HOME

Register Your Facility Registration Requirements

Get Help ?

If you have not paid the annual registration user fee, and you do not have a PIN & PCN, click "FDA User Fee website" to pay the annual registration user fee.

Important Notice: If you are required to pay the establishment registration user fee, you must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you are required to pay the fee and have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility and will need to return and re-enter all information for the facility.

Who Must Pay: All establishments must pay the annual registration fee prior to registering or re-registering.

On the next few pages, you will need to enter the business name and address of your medical device facility. If your facility is local, you will need to enter the address of your facility. If your facility is located outside of the United States, you will need to create a listing for each product that you import or export. For each product that you import or export, you will need to create a listing for each product that you import or export. For each product that you import or export, you will need to create a listing for each product that you import or export.

To determine if your product is exempt, click "premarket notification & approval."

If you need the 3 letter FDA product code, click "product code(s)."

[premarket notification and](#)

[product code\(s\).](#)

To see a list of facility activities and their definitions, click "activities".

- Identify the [activities](#) that you perform on or to the product(s).

If your product is not exempt, you will:

Enter the premarket submission number(s) associated with your product(s).

Enter the proprietary name(s) under which the product is marketed.

Identify the [activities](#) that you perform on or to the product(s).

If your establishment is located outside of the United States, during the listing process you will also identify any importers or persons who offer your devices for import into the United States.

If your establishment is an initial importer - one that takes first title to a product imported into the United States - you will identify the manufacturer for each product being imported.


Click here if you have paid the annual registration user fee and have your PIN & PCN.

[> REGISTER MY FACILITY](#)

Step 7: On the Transfer of Ownership page, select "Yes" or "No" to indicate if the registration is for a facility that you have acquired that is already registered by another company. Then click "Continue Registration". Proceed to Step 8.

If you select "**Yes**" the system will take you through the Transfer of Ownership process. Follow the prompts through the transfer process. If you need assistance, contact reglist@CDRH.FDA.GOV.

DRLM
Device Registration & Listing Module

 **FDA** [FURLS HOME](#)
[DRLM HOME](#)

Register Your Facility
Transfer Of Ownership? [Get Help ?](#)

Is this registration the result of buying a registered facility from another company or merging with another company at this location?

☒ YES ☐ NO

[< BACK](#) [< CANCEL - RETURN to MAIN MENU](#) [> CONTINUE REGISTRATION](#)

Step 8: The Owner/Operator and Official Correspondent Information page displays contact information for both owner/operator and official correspondent. Review for accuracy and then click “Continue Registration.” Proceed to Step 9.

Edit: Edit the information on this form by clicking “Return to Account Management.” When you have completed your edits, **return to Step 2.**

Subaccounts: If there are no subaccounts, the owner/operator contact person’s information will display for both the owner/operator and the official correspondent. If you created sub-accounts, the names associated with the sub-accounts will appear in the dropdown menu along with the owner operator contact person. You can choose any of these people to act as the official correspondent.

Register Your Facility Get Help ?

Owner/Operator and Official Correspondent Information

The [Owner/Operator and Official Correspondent](#) information that you entered when you created or updated your FURLS account is displayed below. To make changes to either the Owner/Operator or the Official Correspondent information, you will need to exit the DRLM section of FURLS and [return to Account Management](#).

Owner/Operator Information

Contact Name: Steven Nagy
Company: SANCO
Address: 12345 Rockville Pike
Rockville, MARYLAND, 20852, UNITED STATES
Telephone: 301-7967814
Fax:
E-mail: steve.nagy@fda.hhs.gov
DUNS Number:

Official Correspondent Information

[Istvan Nagy](#) ▼

Contact Name: Istvan Nagy
Company: SANCO
Address: 12345 Rockville Pike,
Rockville, MARYLAND, 20852, UNITED STATES
Telephone: 301-7967814
Fax:
E-mail: steve.nagy@fda.hhs.gov
DUNS Number:

Callouts:

- If there is at least one subaccount, a dropdown menu displays your choices for official correspondent.
- If information is accurate, click “Continue Registration.”
- Edit this information by clicking “Return to Account Management.”

[< CANCEL - RETURN to MAIN MENU](#) [> CONTINUE REGISTRATION](#)

[< RETURN to ACCOUNT MANAGEMENT](#)

Step 9: On the Location Information page, enter the facility's physical address. If the facility's information matches that of either the owner/operator or official correspondent, click on the radio button next to owner/operator or official correspondent to autofill the location. You must also add any other business trade names for the facility. If known, you may also enter the facility DUNS number and the facility URL. Then, click "Continue Registration." Proceed to Step 10.

Fields marked with an asterisk (*) are required.

Location Information

Register Your Facility

Establishment Information

☒ Same as Owner/Operator ☐ Same as Official Correspondent

Choose Country/Area where Facility is Located:*

UNITED STATES

Facility Name:*

SANCO

Address Line 1:*

12345 Rockville Pike

Address Line 2:

Zip Code:*

20852

City:*

Rockville

State:*

Maryland

Phone:

Area/City Code: 301 Phone Number: 7967814 Extension:

DUNS Number:

(Enter only the 9-digit number, no dashes or other characters)

Click box if this establishment is located in a foreign trade zone:

☐

Facility URL:

Other Business Trade Name(s):

> remove

> Add More Trade Names:

< CLEAR

< BACK

> CONTINUE REGISTRATION

Click "Same as Owner/Operator" or "Same as Official Correspondent" to autofill the facility's address section.

If unable to use the autofill function, enter address and phone number by typing directly into the text boxes.

If known, provide the facility DUNS number and URL.

Other business trade names for the facility must be added in this section.

After you have provided as much facility information as possible, click on "Continue Registration".

Step 10: On the Initial Importer Question page, select **"No"** if 1) the facility does not import medical devices from a foreign country or 2) if there are other activities associated with the devices that it imports. Click "Continue" and skip to Step 12A.

If the facility has no other activities associated with the medical devices that it is importing from a foreign country, select **"Yes"** and proceed to Step 11A.

Register Your Facility

Initial Importer Question

Get Help ?

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

Does this facility import medical devices to the United States from outside the U.S.?

☒ YES ☐ NO

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< CANCEL - RETURN to MAIN MENU

> CONTINUE

Step 11A: If you answered “Yes” to the Initial Importer Question, a list of activities will be displayed. If you perform other activities at this facility on devices that are not imported, select the activities that are performed and click “Continue”. Proceed to Step 12A.

If you **do not perform** any of the listed activities, leave all selections blank and click “Continue.” Proceed to Step 11B.

Register Your Facility

Initial Importer Question

Get Help ?

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

Does this facility import medical devices to the United States from outside the U.S.?

☒ YES ☐ NO

Select all of the following activities that you perform at this facility.
or
Click "Continue" if you do not perform any of these activities:

☐ Manufacture Medical Device
☐ Develop Specifications But Do Not Manufacture At This Facility
☐ Manufacture Medical Device for Another Party (Contract Manufacturer)
☐ Sterilize Medical Device for Another Party (Contract Sterilizer)
☐ Reprocess Single-Use Device
☐ Repack or Relabel Medical Device
☐ Remanufacture Medical Device
☐ Export Device to the United States But Perform No Other Operation on Device
☐ Manufacture Device in the United States for Export Only
☐ Complaint File Establishment per 21 CFR 820.198
☐ Foreign Private Label Distributor

Important Notice: You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility or save any information you have entered and will need to return and re-enter all information for the facility.

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< CANCEL - RETURN to MAIN MENU

> CONTINUE

Step 11B: Click on "Search & Add MFR's Products" and proceed to Step 11C.

Register Your Facility

Identify Manufacturer(s)

Get Help ?

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

All importers must identify the manufacturers of the products that they import on a product-by-product basis. If your company has previously identified manufacturers of products that you import, they will be listed below. You may click "ADD PRODUCTS FROM SELECTED MFR(s)" to select one or more of these manufacturers and identify the products that you import from them, OR you may click "SEARCH & ADD MFR'S PRODUCTS" to identify a different manufacturer whose products you import.

If you have not previously identified a manufacturer from whom you import, please click "SEARCH & ADD MFR'S PRODUCTS" to begin identifying your manufacturer(s).

> SEARCH & ADD MFR'S PRODUCTS

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Step 11C: The Search Manufacturer(s) page provides a variety of ways to add the manufacturer of the imported device. When you have entered the device listing number or entered the manufacturer information, click "Submit." Proceed to Step 11D.

Register Your Facility

Search Manufacturer(s)

Get Help ?

You may search for a particular product by entering the foreign facility's listing number, if known, in the first box below and clicking "SUBMIT".

If you do not know the listing number (the owner of the listing number is the only party that can disclose this information, FDA does not give out this information) or wish to identify multiple products that you import from a manufacturer, you may search for that manufacturer's products by entering identifying information in any of the fields under the "Manufacturer Information" below, then clicking "SUBMIT".

You can also search for manufacturers and products at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.c>

Listing Information

Listing Number

> SUBMIT

Manufacturer Information

Registration Number

9616863

Name

Address

Country/Area

Please select

Postal Code (Must choose Country/Area first)

State (Must choose Country/Area first)

City

For multiple devices or if you do not know the listing number, you can search by MFR registration number or name. Then click "Submit."

In the case of multiple facilities, you can narrow the search by address.

< BACK

> CLEAR

< CANCEL - RETURN TO MAIN MENU

> SUBMIT

Step 11D: On the Importer – Identify Manufacturers of Products page, select the product(s) you import, then click “Add Selected Products.” Proceed to Step 11E.

Register Your Facility

Importer - Identify Manufacturers of Products

Get Help 

Click the check box next to the product(s) you import, then click "ADD SELECTED PRODUCTS."

FACILITY: SHAOXING LIFE SURGICAL DRESSING CO., LTD., NO.1 DAYUAN ST., MAAN TOWN, SHAOXING, ZHEJIANG, ZHEJIANG, --, CHINA

	Product Code	Device Name	Premarket Submission Number	Listing Proprietary Name
<input checked="" type="checkbox"/>	EFN	COTTON, ROLL		View
<input type="checkbox"/>	GDY	GAUZE/SPONGE, INTERNAL, X-RAY DETECTABLE		View
<input type="checkbox"/>	NAB	Gauze/sponge, nonresorbable for external use		View
<input type="checkbox"/>	FQM	BANDAGE, ELASTIC		View
<input type="checkbox"/>	FRL	FIBER, MEDICAL, ABSORBENT		View
<input type="checkbox"/>	KCX	EPILATOR, HIGH FREQUENCY, TWEEZER-TYPE		View
<input type="checkbox"/>	KHA	MASK, SCAVENGING		View
<input type="checkbox"/>	FME	GOWN, EXAMINATION		View
<input type="checkbox"/>	HMP	PAD, EYE		View
<input type="checkbox"/>	HKD	TAPE, NYSTAGMUS		View
<input type="checkbox"/>	KXF	APPLICATOR, ABSORBENT TIPPED, NON-STERILE		View
<input type="checkbox"/>	FMA	DEPRESSOR, TONGUE, NON-SURGICAL		View
<input type="checkbox"/>	KGX	Tape and bandage, adhesive		View
<input type="checkbox"/>	IMD	PACK, HOT OR COLD, DISPOSABLE		View
<input type="checkbox"/>	GFC	DRIVER, SURGICAL, PIN		View

[< BACK](#)

[> ADD SELECTED PRODUCTS](#)

[< CANCEL - RETURN to MAIN MENU](#)

Step 11E: On the Imported Products Summary page, preview the list of manufacturers/devices to ensure all submitted manufacturers / devices are listed. Then, click "Continue." Proceed to Step 16A.

If you need to add more products, click "Search & Add MFR's Products" and return to Step 11C.

Register Your Facility

Imported Products Summary

Get Help ?

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

- Review the products in the "Products Imported" table below.
- Add more products by clicking "SEARCH & ADD PRODUCTS" or "Go to LIST OF MFRS ALREADY IDENTIFIED BY OO".

PRODUCTS IMPORTED:

	Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
<input checked="" type="radio"/>	SHAOXING LIFE SURGICAL DRESSING CO., LTD.	NO.1 DAYUAN ST., MAAN TOWN, SHAOXING, ZHEJIANG, Zhejiang, --, CHINA	EFN	COTTON, ROLL	

> REMOVE THIS PRODUCT

< Go to LIST OF MFRS ALREADY IDENTIFIED BY OO

< CANCEL - RETURN to MAIN MENU

> SEARCH & ADD MFR'S PRODUCTS

> CONTINUE

Step 12A: On the Identify Facility's Products page, click "Add New Product". Proceed to Step 12B.

Register Your Facility

Identify Facility's Products

Get Help ?

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

Important Notice: You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility or save any information you have entered and will need to return and re-enter all information for the facility.

No Listings have been entered previously for your company. Select ADD NEW PRODUCT to Continue.

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< CANCEL - RETURN TO MAIN MENU

> ADD NEW PRODUCT

Step 12B: On the Enter Premarket Submission Number page, if the device is not exempt, enter the premarket submission number, and click "Continue." Proceed to Step 13.

If the device is exempt, click "Continue." Proceed to Step 12C.

If the device **is part of a combination product that includes a drug or biologic**, click the box (indicated below).

Register Your Facility
Enter Premarket Submission Number Get Help ?

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

Important Notice: You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility or save any information you have entered and will need to return and re-enter all information for the facility.

For the product you are listing, enter one of the following:

- Premarket Notification (510(k)) number
- Premarket Application (PMA) number
- Product Development Protocol (PDP) number
- Humanitarian Device Exemption (HDE) number
- Investigational New Drug (IND) number
- New Drug Application (NDA) number

If you believe the product you are listing falls under enforcement discretion, preamendment or import for export, please contact the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

If your device is exempt from FDA premarket notification requirements, leave the box empty.

If the product is a combination product, please check the Combination Product checkbox and then click "Continue".

Enter the Premarket Submission Number:

Click this box if your device is part of a combination product that includes a drug or biologic ☐

[< BACK](#) [> CONTINUE](#)

If your device is part of a combination product that includes a drug or biologic, click here. You can view information about combination products at <http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm118332.htm>

Step 12C: On the Exporter Question page, preview the question and click “Yes” or “No.” Click “Continue” to proceed to Step 12D.

Register Your Facility

Exporter Question

Get Help ?

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

Is this device being manufactured solely for export to a foreign country?

☐ YES ☒ NO

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< CANCEL - RETURN to MAIN MENU

> CONTINUE

Step 12D: If the device is exempt, enter the 3 letter FDA product code or word(s) that describe the device in the “Enter the Product Code or a word or words describing the device” text box on the View Listing Product Codes page. Click “Filter” to display a list of products. Proceed to Step 12E.

Register Your Facility

View Listing Product Codes

Get Help

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

Select Product Code(s)

Shorten your search by using the filter option. Type a word or words describing the device and click Filter. A list of product codes and names will appear below. If you already know the correct product code, type the product code in the box and click Filter. Once you have selected a product code and identified the type(s) of combination product(s) this device is a part of, click Continue.

Enter the Product Code or a word or words describing the device:

> FILTER

> CLEAR FILTER

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	Medical Specialty	Product Code	Device/Product Name	Class	Premarket Submission Required
<input type="radio"/>	CLINICAL CHEMISTRY	CKH	Acid phosphatase, beta glycerophosphate	2	enforcement discretion
<input type="radio"/>	CLINICAL CHEMISTRY	CKE	Acid phosphatase, thymolphthale inmonophosphate	2	enforcement discretion
<input type="radio"/>	CLINICAL CHEMISTRY	CKB	Acid phosphatase, beta glycerophosphate	2	enforcement discretion
<input type="radio"/>	CLINICAL CHEMISTRY	CJR	Acid phosphatase, beta glycerophosphate	2	enforcement discretion
<input type="radio"/>	CLINICAL CHEMISTRY	CJN	Acid phosphatase, beta glycerophosphate	2	enforcement discretion
<input type="radio"/>	CLINICAL CHEMISTRY	JFH	Acid phosphatase, beta glycerophosphate	2	enforcement discretion

You will only see this area if you checked the combination product box in step 12B. Click the description that most closely matches your product.

>> Next

Please make a selection or selections below that most closely describe your combination product:

☐ CONVENIENCE KIT OR CO-PACKAGE

☐ PREFILLED DRUG DELIVERY DEVICE/SYSTEM (SYRINGE, PATCH, ETC.)

☐ PREFILLED BIOLOGIC DELIVERY DEVICE/SYSTEM (SYRINGE,PATCH,ETC.)

☐ DEVICE COATED/IMPREGNATED/OTHERWISE COMBINED DRUG

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< CANCEL - RETURN to MAIN MENU

> CONTINUE

Step 12E: Click the radio-button next to your product code, and then click "Continue." Skip to Step 14A.

NOTE: If more than one page of potential product matches is generated, make sure to review all pages until you find the product code that matches your device.

Register Your Facility

View Listing Product Codes

Get Help ?

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

Select Product Code(s)

Shorten your search by using the filter option. Type a word or words describing the device and click Filter. A list of product codes and names will appear below. If you already know the correct product code, type the product code in the box and click Filter. Once you have selected a product code and identified the type(s) of combination product(s) this device is a part of, click Continue.

Enter the Product Code or a word or words describing the device:

> FILTER

> CLEAR FILTER

Displaying Page 1 of 1

	Medical Specialty	Product Code	Device/Product Name	Class	Premarket Submission Required
<input type="radio"/>	GENERAL AND PLASTIC SURGERY	GDX	SCALPEL, ONE-PIECE	1	510(k) exempt
<input checked="" type="radio"/>	GENERAL AND PLASTIC SURGERY	GDZ	HANDLE, SCALPEL	1	510(k) exempt
<input type="radio"/>	GENERAL AND PLASTIC SURGERY	GES	BLADE, SCALPEL	1	510(k) exempt
<input type="radio"/>	GENERAL AND PLASTIC SURGERY	NLQ	Scalpel, ultrasonic, reprocessed	U	510(k)

< BACK

< CANCEL - RETURN to MAIN MENU

> CONTINUE

Step 13: If a valid premarket submission number was entered, the product code will display. If the product code is correct, click "Continue". If you think that an incorrect product code is showing for the premarket submission number entered, contact reglist@CDRH.FDA.GOV for assistance.

If an incorrect premarket submission number was entered, click "Back" to enter the correct number.

Proceed to Step 14A.

Register Your Facility

View Listing Product Codes

Get Help ?

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

Product codes for the non-exempt device **K123456**

Medical Specialty	Product Code	Device/Product Name	Class
GENERAL AND PLASTIC SURGERY	FRO	Dressing, wound, drug	U

< BACK

< CANCEL - RETURN to MAIN MENU

> CONTINUE

Please make a selection or selections below that most closely describe your combination product

☐ CONVENIENCE KIT OR CO-PACKAGE

☐ PREFILLED DRUG DELIVERY DEVICE/SYSTEM (SYRINGE, PATCH, ETC.)

☐ PREFILLED BIOLOGIC DELIVERY DEVICE/SYSTEM (SYRINGE,PATCH,ETC.)

☐ DEVICE COATED/IMPREGNATED/OTHERWISE COMBINED DRUG

☐ DEVICE COATED OR OTHERWISE COMBINED WITH BIOLOGIC

☐ DRUG/BIOLOGIC COMBINATION

☐ SEPARATE PRODUCTS REQUIRING CROSS LABELING

☐ POSSIBLE COMBINATION BASED ON CROSS LABELING OF SEPARATE PRODUCTS

You will only see this area if you checked the combination product box in step 12B. Click the description that most closely matches your product.

Step 14A: On the Select Activities for Listing(s) page, select the activities related to the device at this facility, and then click "Continue."

Proceed to step 14B.

Register Your Facility

Select Activities for Listing(s)

Get Help ?

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

Scroll down to add proprietary names or importers to this listing.

Select all activities related to this device that are performed at your facility.

- ☒ Manufacture Medical Device
- ☐ Develop Specifications But Do Not Manufacture At This Facility
- ☐ Manufacture Medical Device for Another Party (Contract Manufacturer)
- ☐ Sterilize Medical Device for Another Party (Contract Sterilizer)
- ☐ Reprocess Single-Use Device
- ☐ Repack or Relabel Medical Device
- ☐ Remanufacture Medical Device
- ☐ Export Device to the United States But Perform No Other Operation on Device
- ☐ Manufacture Device in the United States for Export Only
- ☐ Complaint File Establishment per 21 CFR 820.198
- ☐ Foreign Private Label Distributor

Important Notice: You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility or save any information you have entered and will need to return and re-enter all information for the facility.

[< BACK](#) [< CANCEL - RETURN to MAIN MENU](#) [> CONTINUE](#)

Step 14B: On the Enter Proprietary Name(s) page, enter the proprietary name(s) in the Proprietary name text box. Click "Add Proprietary Name" to move the entered name up to the Proprietary Name section. If the proprietary name needs to be confidential, check the disclosure statement box. Once all proprietary names have been added, click "Continue". Proceed to step 15.

The screenshot shows the 'Enter Proprietary Name(s)' page. At the top, there is a table with columns: 'Select', 'Proprietary Name', 'Confidential', 'Device labeled for use', and 'Device Identifier'. The first row shows a checkbox, 'SANCO Best', 'N', and an 'EDIT' link. Below the table is a link: '> REMOVE SELECTED PROPRIETARY NAME(S)'. A callout box points to the table with the text: 'Added proprietary names will display here.'

Below the table is a text input field labeled 'Proprietary Name*:' and a checkbox. A callout box points to the checkbox with the text: 'Click this box if the proprietary name needs to be kept confidential.'

Below the text input field is a callout box with the text: 'Enter proprietary names here. Then click "Add Proprietary Name." Repeat for each proprietary name.'

Below the checkbox is a section titled 'Labeling Information - Pilot Program Participants Only'. It contains a dropdown menu labeled 'Is this device labeled for use' with the value '--Please select--'. Below this is a text input field labeled 'Device Identifier:'. A callout box points to this section with the text: 'Do not enter information in this section, unless you are part of the Pilot Program.'

At the bottom of the section are two buttons: 'ADD PROPRIETARY NAME' and 'CLEAR'.

Below this section is a section titled 'Upload Proprietary Names Using Spreadsheet'. It contains a list of instructions:

- Click [here](#) to download a sample spreadsheet in the correct format.
- Enter the proprietary names into the sample Excel spreadsheet or an Excel spreadsheet formatted exactly as shown in the sample.
- Be sure to save your spreadsheet to a place you will remember on your computer.
- Click "Browse" to go to the saved spreadsheet, then click "Upload".

Below the list is a callout box with the text: 'If you have a large list of proprietary names, you can use the option for uploading them in a spreadsheet.'

At the bottom of the page are three buttons: '< BACK', '< CANCEL - RETURN to MAIN MENU', and '> CONTINUE'.

Step 15: On the Review Listings Summary page, review the device listing and click "Continue" if you do not have any more devices to be listed. Proceed to Step 16A.

To add more devices to the list, click "Add New Product", go to step 12A.

Register Your Facility

Listings Summary

Get Help ?

FACILITY: *SANCO, ROCKVILLE , MARYLAND , UNITED STATES*

- Review the listings in the "Added Listing(s)" table below.
- Make corrections by selecting a listing and clicking "Edit Selected Listing".
- Add more listings by clicking "Add New Product".

	Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Proprietary Names
<input type="radio"/>	New Listing	Exempt	GDZ	HANDLE, SCALPEL	Manufacturer	View All

> REMOVE this PRODUCT from FACILITY'S LISTINGS

< Go to OWNER OPERATOR LIST

< CANCEL - RETURN to MAIN MENU

> EDIT SELECTED LISTING

> ADD NEW PRODUCT

> CONTINUE

Step 16A: On the **top half** of the Registration Review page, review the facility and contact person information for accuracy. If the information is not accurate, click the appropriate “Edit” button and follow the prompts to make corrections. Proceed to Step 16B.

Register Your Facility

Registration Review

FACILITY: *SANCO, ROCKVILLE, MARYLAND, UNITED STATES*

Important Notice: You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If

Facility

> EDIT

Registration Number:

Initial Importer: N

Facility Name: SANCO

Address: 12345 Rockville Pike

DUNS Number: Rockville , Maryland , 20852 , UNITED STATES

Owner/Operator Information

Contact Name: Steven Nagy

Company: SANCO

Address: 12345 Rockville Pike

Telephone: Rockville , MARYLAND , 20852 , UNITED STATES

Fax: 301 - 7967814

E-mail: steve.nagy@fda.hhs.gov

Official Correspondent Information > EDIT

Contact Name: Istvan Nagy

Company: SANCO

Address: 12345 Rockville Pike

Telephone: Rockville , MARYLAND, 20852 , UNITED STATES

Fax: 301 - 7967814

E-mail: steve.nagy@fda.hhs.gov

Step 16B: On the **bottom half** of the Registration Review page, review Imported Products & Manufacturers and Device Listings. If the information is not accurate, click the appropriate "Edit" button and follow the prompts to make corrections. If / when all information is correct, click the box next to the certification statement, and then click "Submit." Proceed to Step 17.

Imported Products and Manufacturers

> ADD OR DELETE

Manufacturer (s) Name	Address	Product Code	Device Name	Submission Number
SHAOXING LIFE SURGICAL DRESSING CO., LTD.	NO.1 DAYUAN ST., MAAN TOWN, SHAOXING, ZHEJIANG, Zhejiang, --, CHINA	EFN	COTTON, ROLL	

Device Listings

> ADD, EDIT OR DELETE

Listing Number	Premarket Submission Number/Type	Product Codes	Device Name	Manufacturer
New Listing	Exempt	GDZ	HANDLE, SCALPEL	

Certification Statement

☐ By clicking the Submit button, I certify that the registration and listing information for this medical device facility, as shown on this page, is true. I understand that the submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.

Important Notice: You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility and will need to return and re-enter all information for the facility.

Who Must Pay: All establishments must pay the annual registration fee prior to registering or re-registering.

If you have already registered for the current fiscal year, you do not need to provide your Payment Identification Number (PIN) and PCN again.

< CANCEL - RETURN to MAIN MENU

> SUBMIT

This section only appears if you identified your facility as an importer.

This section only appears if you indicated activities other than importing.

Step 17: On the Enter Payment Confirmation Number page, enter the 8-digit Payment ID Number (PIN) and 8-digit Payment Confirmation Number (PCN) and click "Submit." Proceed to Step 18.

Register Your Facility

Enter Payment Confirmation Number

Get Help ?

Enter your Payment Identification Number (PIN) and Payment Confirmation Number (PCN) for each registration shown below.

The PIN is a 8-digit number beginning with the number 5. The PCN is an 8-digit number beginning with the two character fiscal year - for 2014, the PCN begins with "14".

You must have a separate PCN for each registration shown. If you have not yet paid your annual registration user fee, you must visit the [FDA User Fee website](#) and pay for each registered facility prior to completing registration. If you have paid for your registration(s) and do not have your PIN and PCN, you can display your numbers by visiting the [FDA User Fee website](#)

Sample PIN - PCN:50000000-14000000

Registration Number	Address	PIN	PCN
New registration being created	SANCO, 12345 Rockville Pike, Rockville, Maryland UNITED STATES	50000000	14000000

< BACK

> SUBMIT

Step 18: The Registration Confirmation page displays the registration information you have entered. Return to the main menu to continue other registration and listing actions or return to the Account Management page to log out of the system. Proceed to Step 19.

Register Your Facility
Registration Confirmation

FACILITY: *SANCO, ROCKVILLE , MARYLAND , UNITED STATES*

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

The Owner/Operator Number for this Registration is: 10047086.

Facility
Registration Number:
Initial Importer: Y
Facility Name: SANCO
Address: 12345 Rockville Pike
DUNS Number: Rockville , Maryland , 20852 , UNITED STATES
Foreign Trade Zone:
Facility URL: N
Other Business Trade Name(s):

Owner/Operator Information
Contact Name: Steven Nagy
Company: SANCO
Address: 12345 Rockville Pike
Telephone: Rockville , MARYLAND , 20852 , UNITED STATES
Fax: 301 - 7967814
E-mail:
DUNS Number: steve.nagy@fda.hhs.gov

Device Listings

Listing Number	Premarket Submission Number	Product Codes	Device Name	Activities
D123456	Exempt	GOZ	HANDLE, SCALPEL	Manufacturer

Imported Products and Manufacturers

Manufacturer (s) Name	Address	Product Code	Dev
SHAOXING LIFE SURGICAL DRESSING CO., LTD.	NO.1 DAYUAN ST., MAAN TOWN, SHAOXING, ZHEJIANG, Zhejiang. --, CHINA	EFN	COTTON, ROLL

Date of Initial Registration: Tue Jun 10 10:23:08 EDT 2014

[< RETURN to MAIN MENU](#)

[< RETURN to ACCOUNT MANAGEMENT](#)

This section only appears if you indicated activities other than importing.

This section only appears if you identified your facility as an importer.

Step 19: A confirmation email will be generated and sent to you with the following information:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Center for Devices and Radiological Health

10903 New Hampshire Ave., WO66 Room 2621

Silver Spring, Maryland 20993-0002

May 30, 2014

Name of Official Correspondent ISTVAN NAGY
Address of Official Correspondent 12345 ROCKVILLE PIKE
ROCKVILLE, MARYLAND 20852
UNITED STATES
STEVE.NAGY@FDA.HHS.GOV

Owner Operator Number 10047086

Dear Sir or Madam,

We have received your registration and listing information for the following medical device establishment

Establishment Name	SANCO
Establishment Address	12345 ROCKVILLE PIKE ROCKVILLE, MARYLAND 20852 UNITED STATES

The information submitted has been processed and entered into the FDA Registration and Device Listing Database. Your device establishment is now considered registered. **You will be notified of your official registration number within 90 days.**

Once you receive a registration number, you are required to re-register on an annual basis from October through December. Failure to re-register every year will invalidate your registration and result in your device establishment and listing information being removed from the FDA Medical Device Registration and Listing Web site.